UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
PO Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,225	08/31/2000	Bharat M. Chowrira	MBHB00-882-C (250/131)	4785

20306 7590 08/22/2003

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER
EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
1635	18

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/653,225	CHOWRIRA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,6-9,16-24 and 29* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6-9 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 2, 6-9, and 29 are currently pending. Claims 16-24 were withdrawn from consideration in Paper No. 15.

Response to Arguments

2. Applicant's arguments with respect to claims 2-3, 6-9, 14, 29, and 31 rejected under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2, 6-9, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cech et al. (US 6,444,650 B1) in view of Joyce et al. (WO 96/17086 A1).

Claim 2 is drawn to an enzymatic nucleic acid molecule, which specifically cleaves RNA derived from a TERT gene, wherein said enzymatic nucleic acid molecule is a DNA enzyme. Claims 6-9 and 29 recite enzymatic molecules comprising at least one modification, or wherein said enzymatic nucleic acid is chemically synthesized.

Cech et al. describe ribozymes comprising 5' and 3' terminal sequences complementary to hTRT (human telomerase reverse transcriptase, see col. 3, lines 32-36) mRNA (see col. 8, lines 39-50). The ribozymes of Cech et al. include those having cleavage sites such as GUA, GUU, and GUC (see col. 8, lines 51-52). However, Cech et al. does not disclose DNAzymes targeting hTERT mRNA.

Joyce et al. teach the design and synthesis of DNAzymes, Figure 8-9 of Joyce et al. describe the core structure of the 10-23 DNAzyme molecules of the present invention comprising the following sequence: 5'-GGCTAGCTACAACGA-3'. Binding arms that comprise about 14 nucleotides that are complementary to sequences in the substrate to be cleaved flanks this DNAzyme sequence. Moreover, the DNAzyme molecules described in the specification as filed, see Table IV, comprise the same core sequence as the 10-23 DNAzyme of Joyce et al.

Joyce et al. also disclose wherein the enzymatic molecule is chemically synthesized (page 43, line 7); and wherein said enzymatic nucleic acid molecule comprises nucleotide analogs, wherein said nucleotide analog encompasses altered bases, different sugars (for example 2'-O-methylcytidine or 2'-O-methylguanosine), altered phosphate backbones, or any combination thereof (see page 17, lines 30-37; and page 18, Table 1). Additionally, Joyce et al. contemplates wherein the DNAzymes are used within cells present inside a cell, including plant, animal, yeast and bacterial cells (see page 26, lines 10-14). See also Figure 9 of Joyce et al., the 10-23 DNAzyme of Joyce et al. cleaves an RNA substrate at a GUA codon, as observed for the ribozymes of Cech et al.

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the teachings of Cech et al. with the teachings of Joyce et al. in the design of the enzymatic nucleic acid molecules according to the present invention. One of ordinary skill in the art at the time of filing would have been motivated to modify the enzymatic nucleic acid molecules of Cech et al. which target hTERT mRNA, to comprise a DNAzyme structure according to Joyce et al. which targets hTERT mRNA, because DNAzymes (i.e. DNA enzymes)

offer several important advantages compared to other macromolecular catalysts, including ribozymes as recited in Cech et al. First, they are easy to prepare, in an era when most laboratories have access to an automated DNA synthesizer and the cost of DNA phosphoramidites has become quite modest. Second, they are very stable compounds, especially compared to RNA, thus facilitating their use in biophysical studies. Third, in vitro selection could be carried out with DNA analogues, including compounds that are nuclease resistant such as phosphorothioate-containing DNA. Finally, DNA enzymes offer a new window on our understanding of the macromolecular basis of catalytic function (page 43, lines 5-18).

Furthermore, it would have been obvious to one of ordinary skill in the art to substitute one functionally equivalent nucleic acid catalyst for another since the DNAzymes of Joyce et al. are disclosed as being functionally equivalent to the ribozymes of Cech et al.

Therefore, the invention as a whole is *prima facie* obvious over Cech et al. in view of Joyce et al.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE